

-1-

| | |
|--------------------------|---|
| Date: <u>May 7, 1999</u> | Express Mail Label No. <u>EL192705426US</u> |
|--------------------------|---|

Inventors: William Cohn
Attorney's Docket No.: BIH97-04A2

SURGICAL RETRACTOR

RELATED APPLICATIONS

This application is a continuation application of International Application No. PCT/US98/08348, filed on April 24, 1998 and designating the United States which is a
5 continuation-in-part application of U.S. Serial No. 08/845,333⁶⁰²³³⁶² filed on April 25, 1997, the entire teachings of the above applications being incorporated herein by reference.

BACKGROUND OF THE INVENTION

Numerous devices have been used to position tissue at a surgical site to aid in the performing of surgical procedures. Retractors, for example, have been used to hold
10 an artery in position during operations adjacent to the heart to prevent movement of the artery. This serves to minimize the risk of injury to the artery and adjacent tissue and can facilitate the desired anastomosis.

A recently developed procedure, referred to as the minimally invasive direct coronary artery bypass procedure, has been used to graft onto a coronary artery without
15 cardiopulmonary bypass. This procedure involves the grafting of the left internal mammary artery (LIMA) onto the left anterior descending (LAD) or other artery. As this procedure does not require the use of a heart lung machine to oxygenate and pump blood, the morbidity and mortality associated with this procedure is substantially lower than previous bypass techniques. A problem associated with the minimally invasive
20 procedure, however, is that while the heart continues to pump during the procedure, the

0030195-0000

motion of the heart can interfere with the surgeon's task of attaching the LIMA to the LAD. There is also a need to stop blood flow in the area of the graft to maintain a clear field of view and provide precise suture placement.

Two basic strategies have been employed to address the problem of operating on a moving site, one being the use of pharmacological agents to limit heart motion, and the other being mechanical, such as a two prong retractor that is pushed down against the heart on both sides of the artery, or alternatively, upward traction away from the moving heart by traction tape or suture thread. Both of these options, however, have problems associated with them. Both options are susceptible to some movement of the vessel grafting site. The use of pharmacological agents is undesirable and impairs circulatory function. Traction by compression of the heart against the spine does serve to immobilize the site but can compromise the ability of the heart to maintain circulation and result in hypotension. Upward traction can involve circumferential compression of the artery to occlude the artery and prevent blood flow, however upward traction that is sufficient to immobilize the site can cause injury, stenosis or occlusion of the vessel.

There is a continuing need however for improvement in devices and methods for retaining tissue at surgical sites to further reduce the risks associated with surgical procedures where the devices and methods are inexpensive, safe and reliable.

SUMMARY OF THE INVENTION

The present invention relates to a surgical retractor for immobilizing tissue at a surgical site and to a method of using the retractor during a surgical procedure. A preferred embodiment of the retractor includes a retaining element having an aperture that exposes the surgical site and a holder that is used to position tissue at the surgical site relative to the retaining element. A handle can be attached to or fabricated with the

retaining element or platform so that the user can manipulate the position of the retractor as needed.

In a preferred embodiment of the invention a connector such as elastic tape or thread is used to position tissue at the surgical site within the retractor aperture and to prevent movement of the tissue during the procedure. The connecting cord, thread or tape also aids in the compression of the artery in a grafting procedure to occlude flow on one or both sides of the surgical site. The cord is attached to the holder on the retaining element. A preferred embodiment of the holder can be a plurality of slits or openings positioned on both sides of the retractor that receive and frictionally secure the cord on both sides of the aperture. In another preferred embodiment a mechanical fastener is used to grip both sides of the cord. The fastener can be a spring mounted valve, for example, that allows the user to adjust the tension in the cord.

A preferred embodiment of the invention comprises a retaining element or base having two sections that can be separated after the procedure is complete to permit removal of the retractor from under the grafted artery. Another preferred embodiment uses a side opening in the platform of the retractor that extends to the aperture so that the grafted artery slips through the side opening during removal. During minimally invasive direct coronary artery bypass operations, one or more surface sections of the retractor platform can be positioned against the inner surface or posterior aspect of one or both ribs adjacent to the surgical site. Thus, the size and geometry of the platform are selected to utilize the adjoining ribs where the upper surface of the platform frictionally engages the inner surface one or more ribs to hold the retractor in a fixed position. The retractor can be beneficial in any procedure where it is necessary to stabilize a surgical site. For example, the retractor can also be used for grafting onto the diagonal, right or other coronary arteries without altering the heart's pumping function.

The coronary arteries are about 1-2mm in diameter, and the pumping heart can move these arteries over distances of several millimeters during each heartbeat. As the movement of even 1 or 2 millimeters can result in a displacement of the grafting site that can substantially interfere with effective anastomosis, it is desirable to restrain
5 movement of the artery at the surgical site in any direction to less than 1mm. The retractor of the present invention restrains movement in the plane of the base to less than 0.5 mm, and preferably less than 0.2 mm.

In a preferred embodiment of the invention, the handle or articulating arm that is secured to the platform can be held in position by the user, attached to a frame that is
10 fixed around the operative site or simply clipped to a drape around the site.

When used in a minimally invasive coronary bypass procedure, the retractor is positioned to expose the left anterior descending (LAD) artery grafting site after incision, removal of the rib section and dissection of the left internal mammary artery (LIMA) from the chest wall. A pair of cords, for example, sialastic tape (i.e. a silicon
15 elastomer) or suture thread, are passed through the myocardium at two locations flanking the artery grafting site with blunt needles. The four ends of the two cords are connected to the platform holder with sufficient tension to occlude blood flow on both sides of the operative site. The tapes compress the artery against the bottom surface of the platform while they hold the artery grafting site in a fixed position relative to the
20 aperture. The coronary artery is opened longitudinally and the end of the mammary artery is sewn to the graft opening with multiple fine sutures. The cords are released, blood flow is restored and the anastomosis is inspected for hemostatis and other defects and the wound is closed.

The platform can include tabs or cord retainers that extend into the aperture to
25 provide a surface against which the arteries can be compressed.

09307105-030799
052050-56720660

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a surgical retractor in accordance with a preferred embodiment of the invention.

Figure 2 is a perspective view of a surgical site illustrating a surgical procedure.

5 Figure 3 is a perspective view of a surgical retractor for a grafting procedure in accordance with the invention.

Figure 4 is a bottom perspective view of a surgical retractor in accordance with the invention.

10 Figure 5 is a cross-sectional view of a surgical retractor during a surgical procedure.

Figures 6A and 6B are partial cross-sectional views of a holder in accordance with the invention.

Figure 7 is a top view of a two piece retainer in accordance with the invention.

15 Figure 8 is a top perspective view of another preferred embodiment of a surgical retractor in accordance with the invention.

Figure 9 is a top perspective view of another preferred embodiment of a surgical retractor in accordance with the invention.

Figure 10 is a schematic diagram illustrating a surgical procedure in accordance with the invention.

20 Figure 11 is a perspective view of a frame supporting a retractor in accordance with the invention.

Figure 12A and 12B are enlarged detailed views of a surgical retractor in accordance with the invention.

25 The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference

00207195 050799
662050 55720260

characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

DETAILED DESCRIPTION OF THE INVENTION

5 A preferred embodiment of the invention is illustrated in connection with Figure 1. A retractor 10 includes a retaining element or base 12 having an aperture 16 that is positioned to expose tissue at a surgical site. The base 12 can be made with a metal or a molded plastic material. The retractor 10 can be sterilized after each use, or alternatively, can be disposable after one procedure. A handle 30 or articulating arm
10 can be permanently attached to the base 12, or as described below in connection with other preferred embodiments, can be detachable.

A suction tube 32 can be attached to the handle 30 or integrated therein and is used to remove material such as blood from the operative site. In this particular embodiment the tube 32 is connected at one end to a tube 34 from a suction pump and
15 connected at a second end to a port 36 in fluid communication with a channel within tube 28 that extends around the periphery of base 12. The peripheral tube can have small openings 38 positioned on the sides or top thereof through which fluid such as blood or other debris can be suctioned from the surgical site to maintain a clear field.

A preferred embodiment of the invention can be used at a surgical site 50 such
20 as the example illustrated in Figure 2. In this particular procedure for a coronary graft without cardiopulmonary bypass, a section of the 4th costal cartilage or rib 56 is removed to expose a section of the LAD artery 61.

A proximal portion of the LIMA 62 is dissected from the chest wall to expose an end 65 to be grafted onto a grafting site 60 on artery 61. Blood flow in vessel 62 can be
25 occluded with a clamp 64.

09307195 050799
662050 56720E60

In this example, a connector such as a pair of cords or sialastic tapes 70, 72 are threaded through myocardium surface 78 under the artery 61 at two locations 74, 76 on opposite sides of the grafting site 60. Note that the exposed surface 78 of heart 52 is undergoing substantial movement during the procedure.

5 As seen in the reverse perspective view of Figure 3 in which the retractor 10 has been inserted and positioned during the procedure, the retractor 10 serves to immobilize the grafting site 60 using connecting tapes 70, 72 which are stretched and attached to a holder mechanism including slots 20a-20d in the peripheral edge of base 12. As described in greater detail below, the slots 20A-20d can be manually opened or closed
10 using actuators 22a-22d, respectively, to allow the user to adjust the tension in the tapes or threads.

The aperture 16 extends longitudinally along the axis of artery 61. The site 60 is preferably located in the plane of the upper surface of base 12. The tapes 70, 72 exert a compressive force on the artery 61 which is pressed against a bottom surface 40 as seen
15 in Figure 4. More particularly, the tapes 70, 72 extend in a direction that is substantially perpendicular to the artery 61 axis exposed in the aperture 16. The aperture can have a first pair of lateral sections 18a and 18b which are aligned to accommodate the positioning of tape 70 and the aperture can also have a second pair of lateral sections 18c and 18d to accommodate the positioning of tape 72. Alternatively, holes extending
20 through the base 12 that are separated from the aperture can be used. The holes are large enough to provide easy feed through and can be angled towards the bottom center to provide compression of the artery at lower tension of the cord.

The size of the aperture can be in the range of 1-3cm in length and 5-15mm in width. The aperture can be narrower in the center and wider at the opposite ends to
25 accommodate the openings or sections 18a-18d.

00307105:050799
66205056720660

The fastening mechanism is illustrated in the partial cross-sectional views of Figures 6A and 6B. The closed position 110 is illustrated in Figure 6A where spring 112 has expanded to move slot 116 in element 115 out of alignment with slot 114 in the outer tube. The cord 72 is displaced and frictionally grasped by the sliding movement
5 of element 115. The user can manually displace 118 to align slot 114 with slot 116 while compressing spring 112. In the "open" position 120, the cord 72 can be easily removed or pulled through to increase tension.

After the procedure is complete the retractor 10 needs to be removed from the site. In the embodiment of Figure 1, the base 12 can be formed with two sections or
10 plates 14a, 14b. As seen in Figure 7, these components can be separated at joint 25 to allow removal of the retractor 10. The two halves 14a, 14b can be connected with a frictional tube section 96.

In the preferred embodiment illustrated in Figure 8, the retractor 100 can have a plurality of handle attachment sites 102, 104, 106, 108 so that the user can attach the
15 handle 105 at any site to provide the most convenient access to the aperture and facilitate immobilization of other arteries. The handle can alternatively be positioned between the two cords at an orthogonal angle relative to the aperture axis and extending above the top surface of the base.

In another preferred embodiment of the invention illustrated in the perspective
20 view of Figure 9, a retractor 140 has a handle 142, slots 144 located in the plane of the aperture 160 to secure the cords, end sections 162, 164 that engage the ribs 54, 58, tabs 148, 150 for compression of both sides of the artery at the site 60 and a side opening 146 so that the retractor can be removed.

In this embodiment, the LIMA slides out through opening 146 during removal of
25 the retractor after completion of the procedure. This unitary retractor structure 140 can also include various features described previously in connection with the embodiment

09207195-050799
662050-56720560

5

10

20

25

Alternative embodiments involve opening of the chest and positioning the retractor at any exposed site on the heart wall or surrounding areas to immobilize the operative site. The retractor serves to isolate the site and limits or stops motion at the site due to respiratory movement of the lungs or the pumping motion of the heart.

The frame 240 used with the invention includes a bar 242 having an arm 244 extending orthogonally from a first end and attached to a second arm 246 with a thumb screw at a second end. Each arm 244, 246 has a pair of mounting elements 252, 255 on which a pivot rod 256 can be mounted. This rod 256 can be rotated 360 degrees to any desired position such that mounting arm 245 can oriented relative to the surgical site as needed to position the retractor 260. Each arm 244, 246 has a pair of grippers 248, 250 that engage anatomical features such as neighboring ribs at the site to stabilize the frame 240.

25 The post 276 can be pivoted relative to arm 262 by loosening the knob 264, thus
allowing the user to orient the retractor 260 at the site for fine positioning. The post 276

is mounted on a plastic retaining element 270 in this embodiment. The element 270 can be a transparent or opaque molded device that can be separated into two components 272, 274 as described previously. The two components can be attached by friction fit rods 294 that are inserted into holes in element 272. Element 270 can be made with a
5 transparent material to enhance viability at the site.

Both components have raised holder elements 284, 286. Element 284 has a pair of slots 288, 289 that each frictionally grip an end of a cord which extends through the aperture 278 to attach tissue to the retractor. The second end of each cord is gripped by corresponding slots 290, 292 in element 286.

10 Tabs or cord retainers 280, 282 are integrally formed with component 274 and function as described previously. In the detailed partial view of Figure 12B, the front inclined surface can be formed at a shallower angle such that the top ridge 279 is narrower. This embodiment of cord retainer 281 affords easier insertion of cords into the aperture.

15 This embodiment can also be formed with integral suction channels or openings in the top surface of the element 270. A suction tube can be attached through or with the arm 262 or attached to a suction port on element 270.

While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that
20 various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

09307105-05079
664250-56720260